

The MiniMed 2001 and 2007 Implantable Pump Systems are "open-loop" systems, which means the patient must test blood glucose, and based on the results of testing, the pump may be programmed with desired rates of delivery by using its Personal Pump Communicator (PPC).

The pump in each system is a round disc, about 3.2 inches in diameter, about 0.8 inches thick, and about 4 - 6 ounces in weight. The outside case of the pump is made of titanium. Attached to the pump is a soft, thin tube (i.e. catheter) through which the insulin passes from the pump to the peritoneal cavity in the patient's abdomen.

The pump of each system has several components: (1) the medication reservoir, (2) the pumping mechanism, (3) the antenna, (4) the microelectronics, (5) the battery, and (6) the tone transducer. The medication reservoir holds the insulin and is refilled with a special syringe through a fill port on the front of the pump. The pumping mechanism pumps the insulin from the medication reservoir and delivers it through the catheter into the body. The pumping mechanism is designed to deliver a precise amount of insulin every time it pumps. The amount of insulin delivered in each stroke of the pump is called the stroke volume. The antenna receives the radio signals from the PPC and delivers the PPC's programmed message to the microelectronics of the pump. The microelectronics are designed to control the pumping mechanism so that the amount of insulin programmed is the amount delivered. The microelectronics are controlled by commands received from the PPC. In the MM2007, the pump includes an extended memory that holds various pump parameters and programming history. The battery supplies power to the pumping mechanism and microelectronics. The battery in the MM2001 is designed to provide approximately 3 years of service while the battery of the MM2007 is designed to provide seven years or more of service. The tone transducer is a speaker in the pump. It emits audible beeps to confirm the proper operation of the pump and also to alert the patient when the pump needs attention.

The catheter is polyethylene lined silicone rubber. It forms two perpendicular parts: a subcutaneous and an intraperitoneal part. The catheter is attached to the pump with a locking bar. Should a health care team need to know where the catheter is located in the abdomen, a radio-opaque stripe runs the length of the catheter. The

catheter has an access port, which may be used to test the proper operation of the pump and catheter. This access port also allows flushing of the catheter tip.

The Personal Pump Communicator (PPC) is a hand-held device that allows commands to be sent to the pump via radio waves. Commands are transmitted from the PPC to the implanted pump when it is held in the proper position relative to the pump.

The PPC of the MM2001 may be used to do several things, including (1) Deliver or cancel an immediate bolus, (2) Change a basal delivery rate, (3) Deliver or cancel a temporary or delayed basal rate, (4) Silence a pump alarm, and (5) Read the current delivery parameters from the pump.

The PPC of the MM2001 stores various pieces of information, including for example (1) The pump type, (2) The current date and time, (3) The date, time, and amount of the last meal bolus, (4) The current basal rate, (5) The date, time, and amount of the last temporary or delayed basal rate, (6) The current alarm settings, (7) The daily totals of insulin delivery, (8) The activity history including the last 1000 commands that were programmed, (9) The amount of medication remaining in the pump, (10) The maximum meal bolus amount, (11) The maximum basal rate and temporary basal rate, (12) The maximum daily use, (13) The daily total reset time, (14) The insulin concentration, (15) The software program version number, and (16) The tone frequency for the alarm.

The PPC of the MM2001 is about 3.5 inches by about 6.0 inches by about 1.5 inches and weighs about 14 ounces. Its main power supply is a standard 9-volt alkaline battery. There is also an internal back-up battery which maintains the PPC's memory when the main battery is depleted or is being changed. The PPC has an easy to read liquid crystal display (LCD) and a nine-button keypad.

The PPC of the MM2007 may be used to program the pump to do several things, including (1) Deliver an immediate bolus (silent or audio), a square wave, or a dual wave bolus, (2) Deliver from one to 48 basal rates in a profiles per day, (3) Preprogram three basal rate delivery patterns, (4) Deliver a temporary basal rate, (5) Suspend the pump infusion, (6) Record personal events, and (7) Program an Automatic Off function.

The MM2007 PPC also stores important information in its memory (120 days of data). This information includes, among other things, (1) Current Date and Time, (2)

Date, Time, and Amount of the Last Meal Bolus, (3) Current Basal Rate, (4) Daily Totals of Insulin Delivery (basal and bolus amount), (5) Clinical History, (6) Medication Remaining in the Pump, (7) Maximum Meal Bolus, (8) Maximum Basal Rate, and (9) Insulin Concentration.

The MM2007 PPC is about 3.5 inches by about 2.8 inches and weighs about 4.1 ounces. The main power supply is a standard 1.5 volt alkaline battery. There is also an internal back-up battery which maintains the PPC's memory when the main battery is depleted or is being changed. The PPC has an easy to read dot matrix liquid crystal display (LCD) and a four-button keypad. The main screen displays the time (12hr. or 24hr. format), month, day and a variety of icons.

Both systems are preferably used in conjunction with 21 PH U-400 (Hoechst AG) which is a purified and concentrated semi-synthetic human insulin.

The claims for which extension is sought are 1, 2, 3, 15, 16, 18, 19, 20, 31, 32, 41, 44, 45, 65, 66, 71, 77, 101, 102, 105, 106, 108, 221, 222, 224, 225, 226, 237, 238, 247, 248, 260, 263, 264, 284, 285, 290, 296, 320, 321, 324, 325, 327, 350, 388, 389, 394, 400, 428, 429, 433, 434, 439, 445, 448, 449, 461, 462, 464, 465, 466, 477, 478, 487, 490, 491, 529, 530, 533, 534, 536, 538, 559, 560, 572, 574, 575, 576, 587, 597, 600, 601, 618, 619, 624, 630, 633, 634, 637, 638, 640, and 643. A comparison of these claims to the MM2001 and MM2007 products is presented in the following table.

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<p>1. A programmable infusion system for providing medication to a living body of a patient comprising:</p> <p style="padding-left: 40px;">an infusion apparatus for implantation in said living body, said apparatus¹ including</p> <p style="padding-left: 80px;">a medication reservoir for storing selected medication²,</p> <p style="padding-left: 40px;">means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic³,</p> <p style="padding-left: 40px;">command receiver means coupled to said infusion means for receiving command</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known as a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ The IIA of each system includes software, control electronics, and telemetry reception and transmission</p>

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<p>signals, and means for telemetering operational information pertaining to said infusion apparatus out of said living body⁴;</p> <p>command source means external to said living body for transmitting said command signals to be received by said command receiver means; and</p> <p>means for receiving said telemetered operational information external to said living body⁵.</p>	<p>hardware for receiving commands from its PPC and for sending operational information to its PPC. The MM2007 uses a carrier frequency of about 262 kHz while the MM2001 uses a carrier frequency of about 36 kHz. The MM2001 IIA provides current delivery parameters to the PPC upon request. The MM2007 provides, among other things, bolus amount and duration information and daily basal delivery information to the PPC.</p> <p>⁵ The PPC for each system includes software, control electronics, and telemetry reception and transmission hardware that enables transmission of commands to its IIA and reception of operational information from its IIA.</p>
<p>2. A programmable infusion system in accordance with claim 1, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.</p>	<p>The PPC of each system transfers, among other things, rate information (i.e. pump strokes/minute) to its IIA related to basal amounts and extended bolus amounts that are to be delivered.</p>
<p>3. A programmable infusion system in accordance with claim 1, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected one of said medication dose inputs.</p>	<p>The PPC of each system has the ability to receive programming instructions from a patient (i.e. selectable and requestable). These instructions may provide a plurality of different basal rates, bolus amounts, and/or extended bolus amounts and durations.</p> <p>The MM2001 may be programmed to supply, among other things, basal rates ranging about 0.1 units/hour to a predefined maximum (i.e. a plurality of operational medication dose inputs), and bolus amounts with variable duration ranging from about 0.2 units to a predefined maximum over a variable period of time.</p> <p>The MM2007 may be programmed to supply, among other things, basal rates ranging from about 0.2 units to a predefined maximum basal rate in increments of 0.1 units of insulin/half hour (i.e. a plurality of operational medication dose inputs). If a delivery over a predefined time is requested the PPC delivers a rate (quantity/time) to the IIA. Programming of the PPC occurs by pressing selected keys on a keypad using the aid of an LCD that displays amounts being programmed. Once programmed the amounts/rates are transmitted to the IIA.</p>
<p>15. A programmable infusion system in accordance with claim 1, wherein said infusion means comprises a fluid handling mechanism for delivering said selected medication, said operational information including information about the operation of said fluid handling mechanism.</p>	<p>The IIA of each system includes a pulsatile piston pump mechanism as well as a flow path connecting the pump to the reservoir and an output flow path through which medication flows from the pump mechanism to the body of the patient. The IIA also includes a refill port for transferring fluid from outside the body of the IIA into the reservoir. Furthermore, the operational information passed from the IIA to the PPC includes information about the delivery parameters for IIA (e.g. on the MM2007 the numbers of pump strokes delivered and on the MM2001 the delivery parameters currently being used by the pump mechanism).</p>
<p>16. A programmable infusion system in</p>	<p>The IIA of each system includes a pulsatile piston pumping</p>

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accordance with claim 15, wherein said fluid handling mechanism comprises means for pumping said selected medication.	mechanism.
18. A programmable infusion system in accordance with claim 16, wherein said pump means operates in a pulsatile mode.	The IIA of each system operates its pumping mechanism in a pulsatile mode.
19. A programmable infusion system in accordance with claim 18, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.	The IIA of each system operates its piston pump so that a fixed volume of insulin is dispensed with each stroke. The volume is nominally 0.5 μ L but each pump is individually calibrated and an actual stroke volume used in determining how insulin will be delivered.
20. A programmable infusion system in accordance with claim 16, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.	The piston pump in the IIA of each system includes a piston chamber that contains a large volume when the piston is retracted and a small volume when the piston is thrust forward. As the piston is being retracted insulin fills the chamber and as the piston is being thrust forward insulin is forced from the chamber.
31. A programmable infusion system in accordance with claim 19, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.	The catheter of the IIA of each system provides a resistance to flow of insulin that was moved into an outlet port during the stroking of the pump. The outlet port of the IIA of the MM2007 models and latter MM2001 models include compressible gas filled pillows that absorb the volume of the insulin in the outlet port during the relatively rapid pump stroke. As the pillows return to their normal shape they exert a force on the insulin to drive it through the catheter and into the body of the patient. The outlet port of the earlier 2001 models included a flexible body that could elastically deflect to absorb rapidly increased volumes of insulin and then elastically return to its normal shape while forcing insulin through the catheter into the body of the patient. Since the force applied by the deformation is proportional to the deflection, the force applied to the insulin decreases as the insulin is forced through the catheter thereby causing an exponential decay in flow of insulin to the patient.
32. A programmable infusion system in accordance with claim 31, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.	The IIA of each system provides a mechanical resistance in the form of the catheter as a result of its length and small diameter. The IIA of each system also provides a mechanical capacitance circuit in the form of compressible gas filled pillows (MM2007 and later versions of the MM2001) or in the form of a slightly deflectable body (earlier versions of the MM2001).
41. A programmable infusion system in accordance with claim 1, wherein one of said at least one remotely commandable operational characteristic comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is	<p>The IIA of the MM2007 includes predefined basal rate and bolus amount maximums and is programmed to compare received delivery rates/amounts against these maximums, if the commanded amount is greater than its corresponding maximum, the delivery command is not executed.</p> <p>The MM2001 does not provide maximum rate limits in its IIA. Instead it provides, among other things, a maximum basal rate and a maximum bolus amount in its PPC. These</p>

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exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.	maximum rate values are used to limit the rates programmable by the patient which result in a limit on the amount dispensable by the IIA.
44. A programmable infusion system in accordance with claim 41, wherein said preselected medication infusion rate is remotely selectable.	<p>The IIA of the MM2007 can receive updated maximum values for basal rates and bolus amounts from its PPC through a Set Maximum Basal Rate telemetry command or Set Maximum Bolus Amount telemetry command, respectively. These maximum amounts may be programmed into the PPC either by a physician using a supervisor password or by a patient (if the physician sets the appropriate option to allow user programming).</p> <p>The MM2001 allows maximum bolus amount (up to 32 units of insulin) and maximum basal rate (up to 10 units/hour) to be programmed into its PPC.</p>
45. A programmable infusion system in accordance with claim 41, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.	<p>The IIA of the MM2007 can receive a physician/user predefined maximum basal rate value or maximum bolus amount from the PPC. In addition, as the basal rate and bolus commands are received by through RF telemetry with a predefined number of bits that can be used to specify basal and bolus amounts, a fixed upper limit exists that is dictated by the telemetry restrictions. This fixed upper limit sets a limit on the maximum basal rate value and maximum bolus amount that may be specified.</p> <p>The IIA of the MM2001 can pump at a predefined minimum number of seconds between pump strokes (about 5.6 seconds/stroke). As all pump strokes occur based on a currently programmed rate, without a memory for storing quantities of pump strokes that may be delivered at a later time, the minimum number of seconds between pump strokes is in effect a fixed maximum number of pump strokes per unit time (i.e. rate). This fixed maximum limits the effect of the programmable maximums. The PPC of the MM2001 provides an upper limit to the maximum basal rate that may be specified (10 units/Hr) and an upper limit to the maximum bolus amount that may be specified (32 units).</p>
65. A programmable infusion system in accordance with claim 1, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper operational conditions.	<p>The IIA of the MM2007 generates a plurality of alarm patterns to control an audio alarm that is provided within the IIA. For example, this audio alarm is used to provide, among other things, a signal to the patient when the IIA is not operating properly. A first alarm pattern is used to warn the patient that the IIA is not operating in normal state (e.g. a low battery or low reservoir condition has arisen) while a second pattern is used to notify the patient that at least one of the microprocessors in the IIA was reset due to some form of malfunction and that the IIA has entered a non-delivery mode.</p> <p>The IIA of the MM2001 generates a plurality of audio alarms. For example, an audio alarm signal is initially generated with each bolus pump stroke when the battery is low and then after some time starts beeping with every bolus and every basal pump stroke. When the IIA monitoring system detects a hardware failure, an audio alarm is controlled to beep once a second for four minutes then to beep three times every</p>

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	fifteen minutes.
66. A programmable infusion system in accordance with claim 65, further comprising means for delivering said alarm signal pattern to said living body subcutaneously.	The IIA of each system is intended to be implanted subcutaneously and as the alarm generation circuitry and the audio transducer (piezo electric element) are included therein, the alarm signal is applied to the body subcutaneously.
71. A programmable infusion system in accordance with claim 66, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
77. A programmable infusion system in accordance with claim 65, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage detecting means being coupled to said alarm generating means wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
101. A programmable infusion system in accordance with claim 1, further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.	The pressure on the medication reservoir is maintained at below normal atmospheric pressure (i.e. below the internal pressure of the living body) by maintaining a liquid -vapor volume of a selected material that has a pressure of vapor below atmospheric pressure (i.e. about - 4 psi)
102. A programmable infusion system in accordance with claim 101, wherein said pressure maintaining means comprises: a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.	The IIA of each system includes a bellows that is made from thin titanium sheets that collapse as insulin is extracted from the reservoir. The bellows separates the insulin containing chamber from a liquid-vapor volume/pool region that varies as insulin is removed from or added to the insulin containing chamber.
105. A programmable infusion system in accordance with claim 102, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber,	The IIA of each system does include an antechamber through which access is gained to the insulin containing chamber and the IIA does include an inlet valve located between the antechamber and the insulin chamber. The inlet valve is opened when the net pressure exerted by a refill needle pressing on the mechanism exceeds the pressure in the medication chamber by a predetermined amount.

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said reservoir inlet valve being operable when the pressure in said antechamber exceeds the pressure in said medication chamber by more than a predetermined differential.	
106. A programmable infusion system in accordance with claim 105, wherein the volume of said antechamber is less than 10% the volume of said medication chamber.	The volume in the antechamber of each system is less than 10% of the volume of the insulin chamber.
108. A programmable infusion system in accordance with claim 1, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.	The IIA of each system dispenses insulin to the patient using fixed volume pulses.
<p>221. A programmable infusion system for providing medication to a living body of a patient comprising:</p> <p style="padding-left: 40px;">an infusion apparatus for implantation in said living body, said apparatus including¹</p> <p style="padding-left: 80px;">a medication reservoir for storing selected medication²,</p> <p style="padding-left: 40px;">means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having a fluid handling mechanism for delivering said selected medication and at least one remotely commandable operational characteristic³,</p> <p style="padding-left: 40px;">command receiver means coupled to said infusion means for receiving command signals, and</p> <p style="padding-left: 40px;">means for telemetering operational information pertaining to said infusion apparatus out of said living body, said operational information including information about the operation of said fluid handling mechanism of said infusion means⁴;</p> <p style="padding-left: 40px;">command source means external to said living body for transmitting said command signals to be received by said command receiver means; and</p> <p style="padding-left: 40px;">means for receiving said telemetered operational information external to said living body⁵.</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known as a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ The IIA of each system includes software, control electronics, and telemetry reception and transmission hardware for receiving commands from its PPC and for sending operational information to its PPC. The MM2007 uses a carrier frequency of about 262 kHz while the MM2001 uses a carrier frequency of about 36 kHz. The MM2001 IIA provides current delivery parameters to the PPC upon request. The MM2007 provides, among other things, bolus amount and duration information and daily basal delivery information to the PPC.</p> <p>⁵ The PPC for each system includes software, control electronics, and telemetry reception and transmission hardware that enables transmission of commands to its IIA and reception of operational information from its IIA.</p>
222. A programmable infusion system in accordance with claim 221, wherein said fluid handling mechanism comprises means for pumping said selected medication.	The IIA of each system includes a pulsatile piston pumping mechanism.
224. A programmable infusion system in accordance with claim 222, wherein said	The IIA of each system operates its pumping mechanism in a pulsatile mode.

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pump means operates in a pulsatile mode.	
225. A programmable infusion system in accordance with claim 224, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.	The IIA of each system operates its piston pump so that a fixed volume of insulin is dispensed with each stroke. The volume is nominally 0.5 μ L but each pump is individually calibrated and an actual stroke volume used in determining how insulin will be delivered.
226. A programmable infusion system in accordance with claim 222, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.	The piston pump in the IIA of each system includes a piston chamber that contains a large volume when the piston is retracted and a small volume when the piston is thrust forward. As the piston is being retracted insulin fills the chamber and as the piston is being thrust forward insulin is forced from the chamber.
237. A programmable infusion system in accordance with claim 225, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.	The catheter of the IIA of each system provides a resistance to flow of insulin that was moved into an outlet port during the stroking of the pump. The outlet port of the IIA of the MM2007 models and latter MM2001 models include compressible gas filled pillows that absorb the volume of the insulin in the outlet port during the relatively rapid pump stroke. As the pillows return to their normal shape they exert a force on the insulin to drive it through the catheter and into the body of the patient. The outlet port of the earlier 2001 models included a flexible body that could elastically deflect to absorb rapidly increased volumes of insulin and then elastically return to its normal shape while forcing insulin through the catheter into the body of the patient. Since the force applied by the deformation is proportional to the deflection, the force applied to the insulin decreases as the insulin is forced through the catheter thereby causing an exponential decay in flow of insulin to the patient.
238. A programmable infusion system in accordance with claim 237, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.	The IIA of each system provides a mechanical resistance in the form of the catheter as a result of its length and small diameter. The IIA of each system also provides a mechanical capacitance circuit in the form of compressible gas filled pillows (MM2007 and later versions of the MM2001) or in the form of a slightly deflectable body (earlier versions of the MM2001).
247. A programmable infusion system in accordance with claim 221, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.	The PPC of each system transfers, among other things, rate information (i.e. pump strokes/minute) to its IIA related to basal amounts and extended bolus amounts that are to be delivered.
248. A programmable infusion system in accordance with claim 221, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a	The PPC of each system has the ability to receive programming instructions from a patient (i.e. selectable and requestable). These instructions may provide a plurality of different basal rates, bolus amounts, and/or extended bolus amounts and durations.

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<p>plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected one of said medication dose inputs.</p>	<p>The MM2001 may be programmed to supply, among other things, basal rates ranging about 0.1 units/hour to a predefined maximum (i.e. a plurality of operational medication dose inputs), and bolus amounts with variable duration ranging from about 0.2 units to a predefined maximum over a variable period of time.</p> <p>The MM2007 may be programmed to supply, among other things, basal rates ranging from about 0.2 units to a predefined maximum basal rate in increments of 0.1 units of insulin/half hour (i.e. a plurality of operational medication dose inputs). If a delivery over a predefined time is requested the PPC delivers a rate (quantity/time) to the IIA. Programming of the PPC occurs by pressing selected keys on a keypad using the aid of an LCD that displays amounts being programmed. Once programmed the amounts/rates are transmitted to the IIA.</p>
<p>260. A programmable infusion system in accordance with claim 221, wherein one of said at least one remotely commandable operational characteristic comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.</p>	<p>The IIA of the MM2007 includes predefined basal rate and bolus amount maximums and is programmed to compare received delivery rates/amounts against these maximums, if the commanded amount is greater than its corresponding maximum, the delivery command is not executed.</p> <p>The MM2001 does not provide maximum rate limits in its IIA. Instead it provides, among other things, a maximum basal rate and a maximum bolus amount in its PPC. These maximum rate values are used to limit the rates programmable by the patient which result in a limit on the amount dispensable by the IIA.</p>
<p>263. A programmable infusion system in accordance with claim 260, wherein said preselected medication infusion rate is remotely selectable.</p>	<p>The IIA of the MM2007 can receive updated maximum values for basal rates and bolus amounts from its PPC through a Set Maximum Basal Rate telemetry command or Set Maximum Bolus Amount telemetry command, respectively. These maximum amounts may be programmed into the PPC either by a physician using a supervisor password or by a patient (if the physician sets the appropriate option to allow user programming).</p> <p>The MM2001 allows maximum bolus amount (up to 32 units of insulin) and maximum basal rate (up to 10 units/hour) to be programmed into its PPC.</p>
<p>264. A programmable infusion system in accordance with claim 260, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.</p>	<p>The IIA of the MM2007 can receive a physician/user predefined maximum basal rate value or maximum bolus amount from the PPC. In addition, as the basal rate and bolus commands are received by through RF telemetry with a predefined number of bits that can be used to specify basal and bolus amounts, a fixed upper limit exists that is dictated by the telemetry restrictions. This fixed upper limit sets a limit on the maximum basal rate value and maximum bolus amount that may be specified.</p> <p>The IIA of the MM2001 can pump at a predefined minimum number of seconds between pump strokes (about 5.6 seconds/stroke). As all pump strokes occur based on a</p>

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	<p>currently programmed rate, without a memory for storing quantities of pump strokes that may be delivered at a later time, the minimum number of seconds between pump strokes is in effect a fixed maximum number of pump strokes per unit time (i.e. rate). This fixed maximum limits the effect of the programmable maximums. The PPC of the MM2001 provides an upper limit to the maximum basal rate that may be specified (10 units/Hr) and an upper limit to the maximum bolus amount that may be specified (32 units).</p>
<p>284. A programmable infusion system in accordance with claim 221, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper operational conditions.</p>	<p>The IIA of the MM2007 generates a plurality of alarm patterns to control an audio alarm that is provided within the IIA. For example, this audio alarm is used to provide, among other things, a signal to the patient when the IIA is not operating properly. A first alarm pattern is used to warn the patient that the IIA is not operating in normal state (e.g. a low battery or low reservoir condition has arisen) while a second pattern is used to notify the patient that at least one of the microprocessors in the IIA was reset due to some form of malfunction and that the IIA has entered a non-delivery mode.</p> <p>The IIA of the MM2001 generates a plurality of audio alarms. For example, an audio alarm signal is initially generated with each bolus pump stroke when the battery is low and then after some time starts beeping with every bolus and every basal pump stroke. When the IIA monitoring system detects a hardware failure, an audio alarm is controlled to beep once a second for four minutes then to beep three times every fifteen minutes.</p>
<p>285. A programmable infusion system in accordance with claim 284, further comprising means for delivering said alarm signal pattern to said living body subcutaneously.</p>	<p>The IIA of each system is intended to be implanted subcutaneously and as the alarm generation circuitry and the audio transducer (piezo electric element) are included therein, the alarm signal is applied to the body subcutaneously.</p>
<p>290. A programmable infusion system in accordance with claim 285, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.</p>	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
<p>296. A programmable infusion said infusion means and means for determining the voltage of said system in accordance with claim 284, further comprising battery means for powering battery means, said voltage determining means being coupled to said alarm generating means wherein one of said improper operational conditions comprises low battery means voltage.</p>	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the</p>

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	control electronics in the IIA cause the piezo alarm in the IIA to sound.
320. A programmable infusion system in accordance with claim 221, further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.	The pressure on the medication reservoir is maintained at below normal atmospheric pressure (i.e. below the internal pressure of the living body) by maintaining a liquid -vapor volume of a selected material that has a pressure of vapor below atmospheric pressure (i.e. about - 4 psi)
321. A programmable infusion system in accordance with claim 320, wherein said pressure maintaining means comprises: a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.	The IIA of each system includes a bellows that is made from thin titanium sheets that collapse as insulin is extracted from the reservoir. The bellows separates the insulin containing chamber from a liquid-vapor volume/pool region that varies as insulin is removed from or added to the insulin containing chamber.
324. A programmable infusion system in accordance with claim 321, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable when the pressure in said antechamber exceeds the pressure in said medication chamber by more than a predetermined differential.	The IIA of each system does include an antechamber through which access is gained to the insulin containing chamber and the IIA does include an inlet valve located between the antechamber and the insulin chamber. The inlet valve is opened when the net pressure exerted by a refill needle pressing on the mechanism exceeds the pressure in the medication chamber by a predetermined amount.
325. A programmable infusion system in accordance with claim 324, wherein the volume of said antechamber is less than 10% the volume of said medication chamber.	The volume in the antechamber of each system is less than 10% of the volume of the insulin chamber.
327. A programmable infusion system in accordance with claim 221, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.	The IIA of each system dispenses insulin to the patient using fixed volume pulses.
350. A programmable infusion system for providing medication to a living body of a patient comprising: an infusion apparatus for implantation in said living body, said apparatus including ¹ a medication reservoir for storing selected medication ² , means for infusing said selected medication stored in said medication reservoir into said living body, said infusion	¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient. ² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir. ³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The

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<p>means having an infusion rate variable upon command, command receiver means coupled to said infusion means for receiving command signals³,</p> <p>means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means⁴,</p> <p>command source means external to said living body for transmitting said command signals to be received by said command receiver means⁵, and</p> <p>means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected one of said medication dose inputs⁶.</p>	<p>timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ Each system provides mechanisms for inhibiting infusion of insulin if a predefined maximum infusion rate or amount is exceeded. The PPC of each system provides a way of selectively setting maximum basal rates and bolus amounts. These maximum amounts are used by the PPC to limit the amounts that may be programmed into the PPC for delivery by the IIA. Because of the telemetry connection between the PPC and its IIA, these maximum limits are operably coupled to the IIA. Furthermore, in the MM2007 system, these maximum amounts are also transmitted via telemetry to the IIA which uses them to ensure that telemetry messages are not acted upon if they contain delivery commands that call for amounts in excess of these limits. In addition, the MM2001 system sets is configured with a maximum pumping rate of about 10 strokes per minute.</p> <p>⁵ The PPC for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of commands to its IIA.</p> <p>⁶ The PPC of each system has the ability to receive programming instructions from a patient (i.e. selectable and requestable). These instructions may provide a plurality of different basal rates, bolus amounts, and/or extended bolus amounts and durations.</p> <p>The MM2001 may be programmed to supply, among other things, basal rates ranging about 0.1 units/hour to a predefined maximum (i.e. a plurality of operational medication dose inputs), and bolus amounts with variable duration ranging from about 0.2 units to a predefined maximum over a variable period of time.</p> <p>The MM2007 may be programmed to supply, among other things, basal rates ranging from about 0.2 units to a predefined maximum basal rate in increments of 0.1 units of insulin/half hour (i.e. a plurality of operational medication dose inputs). If a delivery over a predefined time is requested the PPC delivers a rate (quantity/time) to the IIA. Programming of the PPC occurs by pressing selected keys on a keypad using the aid of an LCD that displays amounts being programmed. Once programmed the amounts/rates are transmitted to the IIA.</p>
<p>388. A programmable infusion system for providing medication to a living body of a patient comprising: an infusion apparatus for implantation in said living body, said apparatus including¹</p> <p>a medication reservoir for storing selected medication²,</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p>

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<p>means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having an infusion rate variable upon command,</p> <p>command receiver means coupled to said infusion means for receiving command signals³,</p> <p>means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means⁴; and</p> <p>command source means external to said living body for transmitting said command signals to be received by said command receiver means⁵, and</p> <p>means for generating a distinctive alarm signal pattern for each of a plurality of improper operational conditions⁶.</p>	<p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ Each system provides mechanisms for inhibiting infusion of insulin if a predefined maximum infusion rate or amount is exceeded. The PPC of each system provides a way of selectively setting maximum basal rates and bolus amounts. These maximum amounts are used by the PPC to limit the amounts that may be programmed into the PPC for delivery by the IIA. Because of the telemetry connection between the PPC and its IIA, these maximum limits are operably coupled to the IIA. Furthermore, in the MM2007 system, these maximum amounts are also transmitted via telemetry to the IIA which uses them to ensure that telemetry messages are not acted upon if they contain delivery commands that call for amounts in excess of these limits. In addition, the MM2001 system is configured to pump at no more than about 10 strokes per minute.</p> <p>⁵ The PPC for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of commands to its IIA.</p> <p>⁶ The IIA of the MM2007 generates a plurality of alarm patterns to control an audio alarm that is provided within the IIA. For example, this audio alarm is used to provide, among other things, a signal to the patient when the IIA is not operating properly. A first alarm pattern is used to warn the patient that the IIA is not operating in normal state (e.g. a low battery or low reservoir condition has arisen) while a second pattern is used to notify the patient that at least one of the microprocessors in the IIA was reset due to some form of malfunction and that the IIA has entered a non-delivery mode.</p> <p>The IIA of the MM2001 generates a plurality of audio alarms. For example, an audio alarm signal is initially generated with each bolus pump stroke when the battery is low and then after some time starts beeping with every bolus and every basal pump stroke. When the IIA monitoring system detects a hardware failure, an audio alarm is controlled to beep once a second for four minutes then to beep three times every fifteen minutes.</p>
<p>389. A programmable infusion system in accordance with claim 388, further comprising means for delivering said alarm signal pattern to said living body subcutaneously.</p>	<p>The IIA of each system is intended to be implanted subcutaneously and as the alarm generation circuitry and the audio transducer (piezo electric element) are included therein, the alarm signal is applied to the body subcutaneously.</p>
<p>394. A programmable infusion system in accordance with claim 389, further comprising battery means for powering said infusion means and means for determining</p>	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p>

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<p>the voltage of said battery means, said voltage detecting means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.</p>	<p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
<p>400. A programmable infusion system in accordance with claim 388, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means wherein one of said improper operational conditions comprises low battery means voltage.</p>	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
<p>428. A programmable infusion system for providing medication to a living body of a patient comprising:</p> <p style="padding-left: 40px;">an infusion apparatus for implantation in said living body, said apparatus including¹</p> <p style="padding-left: 80px;">a medication reservoir for storing selected medication²,</p> <p style="padding-left: 40px;">means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having an infusion rate variable upon command,</p> <p style="padding-left: 80px;">command receiver means coupled to said infusion means for receiving command signals³, and</p> <p style="padding-left: 40px;">means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means⁴,</p> <p style="padding-left: 80px;">command source means external to said living body for transmitting said command signals to be received by said command receiver means⁵,</p> <p style="padding-left: 40px;">means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body⁶,</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known as a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ Each system provides mechanisms for inhibiting infusion of insulin if a predefined maximum infusion rate or amount is exceeded. The PPC of each system provides a way of selectively setting maximum basal rates and bolus amounts. These maximum amounts are used by the PPC to limit the amounts that may be programmed into the PPC for delivery by the IIA. Because of the telemetry connection between the PPC and its IIA, these maximum limits are operably coupled to the IIA. Furthermore, in the MM2007 system, these maximum amounts are also transmitted via telemetry to the IIA which uses them to ensure that telemetry messages are not acted upon if they contain delivery commands that call for amounts in excess of these limits. In addition, the MM2001 system is configured with a maximum pumping rate of about 10 strokes per minute.</p> <p>⁵ The PPC for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of commands to its IIA.</p>

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<p>wherein said pressure maintaining means comprises:</p> <p>flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber;</p> <p>a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber⁷, and</p> <p>an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable when the pressure in said antechamber exceeds the pressure in said medication chamber by more than a predetermined differential⁸.</p>	<p>⁶ The pressure on the medication reservoir is maintained at below normal atmospheric pressure (i.e. below the internal pressure of the living body) by maintaining a liquid -vapor volume of a selected material that has a pressure of vapor below atmospheric pressure (i.e. about - 4 psi)</p> <p>⁷ The IIA of each system includes a bellows that is made from thin titanium sheets that collapse as insulin is extracted from the reservoir. The bellows separates the insulin containing chamber from a liquid-vapor volume/pool region that varies as insulin is removed from or added to the insulin containing chamber.</p> <p>⁸ The IIA of each system does include an antechamber through which access is gained to the insulin containing chamber and the IIA does include an inlet valve located between the antechamber and the insulin chamber. The inlet valve is opened when the net pressure exerted by a refill needle pressing on the mechanism exceeds the pressure in the medication chamber by a predetermined amount.</p>
<p>429. A programmable infusion system in accordance with claim 428, wherein the volume of said antechamber is less than 10% the volume of said medication chamber.</p>	<p>The volume in the antechamber of each system is less than 10% of the volume of the insulin chamber.</p>
<p>433. A programmable infusion system for providing medication to a living body of a patient comprising:</p> <p>an infusion apparatus for implantation in said living body, said apparatus including¹</p> <p>a medication reservoir for storing selected medication²,</p> <p>means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic³,</p> <p>command receiver means coupled to said infusion means for receiving command signals⁴, and</p> <p>means for generating a distinctive alarm signal pattern for each of a plurality of improper operational conditions in said system⁵; and</p> <p>command source means external to said living body for transmitting said command signals to be received by said command receiver means⁶.</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of medication with each stroke. The timing of and number of strokes dispensed (i.e. commandable operational characteristics) are controlled by commands received the PPC.</p> <p>⁴ The IIA includes software, control electronics, and telemetry reception hardware for receiving commands from the PPC. The MM2007 uses a carrier frequency of about 262 kHz while the MM2001 uses a carrier frequency of about 36 kHz.</p> <p>⁵ The IIA of each system generates at least one audio alarm pattern for some system problems and a different audio alarm pattern for other system anomalies. For example, in the MM2007 system, a first alarm pattern may be used to warn the patient that the IIA is not operating in a normal state (e.g. a low battery or low reservoir condition has arisen) while a second pattern is used to notify the patient that at least one of</p>

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	<p>the microprocessors in the IIA was reset due to some form of malfunction and as such that the IIA has entered a non-delivery mode. Additionally for example, the IIA of the MM2001 generates an audio alarm signal when each bolus pump stroke is delivered when the battery is low and when a IIA monitoring system detects a hardware failure, an audio alarm is controlled to beep once a second for four minutes then to beep three times every fifteen minutes.</p> <p>⁶ The PPC for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of commands to the IIA.</p>
434. A programmable infusion system in accordance with claim 433, further comprising means for delivering said alarm signal pattern to said living body subcutaneously.	The IIA of each system is intended to be implanted subcutaneously and as the alarm generation circuitry and the audio transducer (piezo electric element) are included therein, the alarm signal is applied to the body subcutaneously.
439. A programmable infusion system in accordance with claim 434, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
445. A programmable infusion system in accordance with claim 433, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
448. A programmable infusion system in accordance with claim 433, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.	The PPC of each system transfers, among other things, rate information (i.e. pump strokes/minute) to its IIA related to basal amounts and extended bolus amounts that are to be delivered.
449. A programmable infusion system in accordance with claim 433, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered	The PPC of each system has the ability to receive programming instructions from a patient (i.e. selectable and requestable). These instructions may provide a plurality of different basal rates, bolus amounts, and/or extended bolus amounts and durations.

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operational information external to said living body, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected one of said medication dose inputs.	<p>The MM2001 may be programmed to supply, among other things, basal rates ranging about 0.1 units/hour to a predefined maximum (i.e. a plurality of operational medication dose inputs), and bolus amounts with variable duration ranging from about 0.2 units to a predefined maximum over a variable period of time.</p> <p>The MM2007 may be programmed to supply, among other things, basal rates ranging from about 0.2 units to a predefined maximum basal rate in increments of 0.1 units of insulin/half hour (i.e. a plurality of operational medication dose inputs). If a delivery over a predefined time is requested the PPC delivers a rate (quantity/time) to the IIA. Programming of the PPC occurs by pressing selected keys on a keypad using the aid of an LCD that displays amounts being programmed. Once programmed the amounts/rates are transmitted to the IIA.</p>
461. A programmable infusion system in accordance with claim 433, wherein said infusion means comprises a fluid handling mechanism for delivering said selected medication, said operational information including information about the operation of said fluid handling mechanism.	The IIA of each system includes a pulsatile piston pump mechanism as well as a flow path connecting the pump to the reservoir and an output flow path through which medication flows from the pump mechanism to the body of the patient. The IIA also includes a refill port for transferring fluid from outside the body of the IIA into the reservoir. Furthermore, the operational information passed from the IIA to the PPC includes information about the delivery parameters for IIA (e.g. on the MM2007 the numbers of pump strokes delivered and on the MM2001 the delivery parameters currently being used by the pump mechanism).
462. A programmable infusion system in accordance with claim 461, wherein said fluid handling mechanism comprises means for pumping said selected medication.	The IIA of each system includes a pulsatile piston pumping mechanism.
464. A programmable infusion system in accordance with claim 462, wherein said pump means operates in a pulsatile mode.	The IIA of each system operates its pumping mechanism in a pulsatile mode.
465. A programmable infusion system in accordance with claim 464, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.	The IIA of each system operates its piston pump so that a fixed volume of insulin is dispensed with each stroke. The volume is nominally 0.5 μ L but each pump is individually calibrated and an actual stroke volume used in determining how insulin will be delivered.
466. A programmable infusion system in accordance with claim 462, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.	The piston pump in the IIA of each system includes a piston chamber that contains a large volume when the piston is retracted and a small volume when the piston is thrust forward. As the piston is being retracted insulin fills the chamber and as the piston is being thrust forward insulin is forced from the chamber.
477. A programmable infusion system in accordance with claim 465, further comprising means for feeding said selected medication into said living body from said	The catheter of the IIA of each system provides a resistance to flow of insulin that was moved into an outlet port during the stroking of the pump. The outlet port of the IIA of the MM2007 models and latter MM2001 models include

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pump means in a flow which decays exponentially over time.	compressible gas filled pillows that absorb the volume of the insulin in the outlet port during the relatively rapid pump stroke. As the pillows return to their normal shape they exert a force on the insulin to drive it through the catheter and into the body of the patient. The outlet port of the earlier 2001 models included a flexible body that could elastically deflect to absorb rapidly increased volumes of insulin and then elastically return to its normal shape while forcing insulin through the catheter into the body of the patient. Since the force applied by the deformation is proportional to the deflection, the force applied to the insulin decreases as the insulin is forced through the catheter thereby causing an exponential decay in flow of insulin to the patient.
478. A programmable infusion system in accordance with claim 477, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.	The IIA of each system provides a mechanical resistance in the form of the catheter as a result of its length and small diameter. The IIA of each system also provides a mechanical capacitance circuit in the form of compressible gas filled pillows (MM2007 and later versions of the MM2001) or in the form of a slightly deflectable body (earlier versions of the MM2001).
487. A programmable infusion system in accordance with claim 433, wherein one of said at least one remotely commandable operational characteristic comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.	<p>The IIA of the MM2007 includes predefined basal rate and bolus amount maximums and is programmed to compare received delivery rates/amounts against these maximums, if the commanded amount is greater than its corresponding maximum, the delivery command is not executed.</p> <p>The MM2001 does not provide maximum rate limits in its IIA. Instead it provides, among other things, a maximum basal rate and a maximum bolus amount in its PPC. These maximum rate values are used to limit the rates programmable by the patient which result in a limit on the amount dispensable by the IIA.</p>
490. A programmable infusion system in accordance with claim 487, wherein said preselected medication infusion rate is remotely selectable.	<p>The IIA of the MM2007 can receive updated maximum values for basal rates and bolus amounts from its PPC through a Set Maximum Basal Rate telemetry command or Set Maximum Bolus Amount telemetry command, respectively. These maximum amounts may be programmed into the PPC either by a physician using a supervisor password or by a patient (if the physician sets the appropriate option to allow user programming).</p> <p>The MM2001 allows maximum bolus amount (up to 32 units of insulin) and maximum basal rate (up to 10 units/hour) to be programmed into its PPC.</p>
491. A programmable infusion system in accordance with claim 487, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.	<p>The IIA of the MM2007 can receive a physician/user predefined maximum basal rate value or maximum bolus amount from the PPC. In addition, as the basal rate and bolus commands are received by through RF telemetry with a predefined number of bits that can be used to specify basal and bolus amounts, a fixed upper limit exists that is dictated by the telemetry restrictions. This fixed upper limit sets a limit on the maximum basal rate value and maximum bolus amount that may be specified.</p> <p>The IIA of the MM2001 can pump at a predefined minimum</p>

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	number of seconds between pump strokes (about 5.6 seconds/stroke). As all pump strokes occur based on a currently programmed rate, without a memory for storing quantities of pump strokes that may be delivered at a later time, the minimum number of seconds between pump strokes is in effect a fixed maximum number of pump strokes per unit time (i.e. rate). This fixed maximum limits the effect of the programmable maximums. The PPC of the MM2001 provides an upper limit to the maximum basal rate that may be specified (10 units/Hr) and an upper limit to the maximum bolus amount that may be specified (32 units).
529. A programmable infusion system in accordance with claim 433, medication reservoir at a pressure level below the internal pressure of said living body.	The pressure on the medication reservoir is maintained at below normal atmospheric pressure (i.e. below the internal pressure of the living body) by maintaining a liquid -vapor volume of a selected material that has a pressure of vapor below atmospheric pressure (i.e. about - 4 psi)
530. A programmable infusion system in accordance with claim 529, wherein said pressure means comprises: a flexible maintaining diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.	The IIA of each system includes a bellows that is made from thin titanium sheets that collapse as insulin is extracted from the reservoir. The bellows separates the insulin containing chamber from a liquid-vapor volume/pool region that varies as insulin is removed from or added to the insulin containing chamber.
533. A programmable infusion system in accordance with claim 530, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable when the pressure in said antechamber exceeds the pressure in said medication chamber by more than a predetermined differential.	The IIA of each system does include an antechamber through which access is gained to the insulin containing chamber and the IIA does include an inlet valve located between the antechamber and the insulin chamber. The inlet valve is opened when the net pressure exerted by a refill needle pressing on the mechanism exceeds the pressure in the medication chamber by a predetermined amount.
534. A programmable infusion system in accordance with claim 533, wherein the volume of said antechamber is less than 10% the volume of said medication chamber.	The volume in the antechamber of each system is less than 10% of the volume of the insulin chamber.
536. A programmable infusion system in accordance with claim 433, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.	The IIA of each system dispenses insulin to the patient using fixed volume pulses.
538. A programmable infusion system for providing medication to a living body of a patient comprising: an infusion apparatus for implantation in said living body, said	¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known a Personal Pump Communicator (PPC). These systems dispense insulin to the

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<p>apparatus including¹</p> <p>a medication reservoir for storing selected medication²,</p> <p>means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic and including means for pumping a preselected amount of medication into said living body³,</p> <p>means for recording the rate at which pumping is effected by said pump means⁴, and</p> <p>command receiver means coupled to said infusion means for receiving command signals⁵; and</p> <p>command source means external to said living body for transmitting said command signals to be received by said command receiver means⁶.</p>	<p>body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of medication with each stroke. The timing of and number of strokes dispensed are controlled by commands received its PPC.</p> <p>⁴ Each system provides a mechanism for recording pumping rates used by its IIA. For example, the IIA of the MM2007 includes several counters which count pump strokes. One counter counts pump strokes that have been delivered in association with basal rate deliveries during the course of each day, another counts the number of pump strokes delivered in association with bolus deliveries each day, and a third provides a count of the total pump strokes delivered. Additionally the PPC of the MM2001 provides daily totals for insulin delivery and a record of recent commands.</p> <p>⁵ The IIA of each system includes software, control electronics, and telemetry reception hardware for receiving commands from its PPC. The MM2007 uses a carrier frequency of about 262 kHz and a data transmission frequency of about 8 kHz while the MM2001 uses a carrier frequency of about 36 kHz and a data transmission frequency of about 1 - 2 kHz.</p> <p>⁶ The PPC for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of commands to the IIA.</p>
<p>559. A programmable infusion system in accordance with claim 538, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.</p>	<p>The PPC of each system transfers, among other things, rate information (i.e. pump strokes/minute) to its IIA related to basal amounts and extended bolus amounts that are to be delivered.</p>
<p>560. A programmable infusion system in accordance with claim 538, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and</p>	<p>The PPC of each system has the ability to receive programming instructions from a patient (i.e. selectable and requestable). These instructions may provide a plurality of different basal rates, bolus amounts, and/or extended bolus amounts and durations.</p> <p>The MM2001 may be programmed to supply, among other things, basal rates ranging about 0.1 units/hour to a predefined maximum (i.e. a plurality of operational medication dose inputs), and bolus amounts with variable duration ranging from about 0.2 units to a predefined maximum over a variable period of time.</p> <p>The MM2007 may be programmed to supply, among other</p>

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requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected one of said medication dose inputs.	things, basal rates ranging from about 0.2 units to a predefined maximum basal rate in increments of 0.1 units of insulin/half hour (i.e. a plurality of operational medication dose inputs). If a delivery over a predefined time is requested the PPC delivers a rate (quantity/time) to the IIA. Programming of the PPC occurs by pressing selected keys on a keypad using the aid of an LCD that displays amounts being programmed. Once programmed the amounts/rates are transmitted to the IIA.
572. A programmable infusion system in accordance with claim 538, wherein said infusion means comprises a fluid handling mechanism, said fluid handling mechanism including said pump means, said operational information including information about the operation of said fluid handling mechanism.	The IIA of each system includes a pulsatile piston pump mechanism as well as a flow path connecting the pump to the reservoir and an output flow path through which medication flows from the pump mechanism to the body of the patient. The IIA also includes a refill port for transferring fluid from outside the body of the IIA into the reservoir. Furthermore, the operational information passed from the IIA to the PPC includes information about the delivery parameters for IIA (e.g. on the MM2007 the numbers of pump strokes delivered and on the MM2001 the delivery parameters currently being used by the pump mechanism.
574. A programmable infusion system in accordance with claim 572, wherein said pump means operates in a pulsatile mode.	The IIA of each system operates its pumping mechanism in a pulsatile mode.
575. A programmable infusion system in accordance with claim 574, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.	The IIA of each system operates its piston pump so that a fixed volume of insulin is dispensed with each stroke. The volume is nominally 0.5 μ L but each pump is individually calibrated and an actual stroke volume used in determining how insulin will be delivered.
576. A programmable infusion system in accordance with claim 575, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.	The piston pump in the IIA of each system includes a piston chamber that contains a large volume when the piston is retracted and a small volume when the piston is thrust forward. As the piston is being retracted insulin fills the chamber and as the piston is being thrust forward insulin is forced from the chamber.
587. A programmable infusion system in accordance with claim 575, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.	The catheter of the IIA of each system provides a resistance to flow of insulin that was moved into an outlet port during the stroking of the pump. The outlet port of the IIA of the MM2007 models and latter MM2001 models include compressible gas filled pillows that absorb the volume of the insulin in the outlet port during the relatively rapid pump stroke. As the pillows return to their normal shape they exert a force on the insulin to drive it through the catheter and into the body of the patient. The outlet port of the earlier 2001 models included a flexible body that could elastically deflect to absorb rapidly increased volumes of insulin and then elastically return to its normal shape while forcing insulin through the catheter into the body of the patient. Since the force applied by the deformation is proportional to the deflection, the force applied to the insulin decreases as the insulin is forced through the catheter thereby causing an

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	exponential decay in flow of insulin to the patient.
597. A programmable infusion system in accordance with claim 538, wherein one of said at least one remotely commandable operational characteristic comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means.	<p>The IIA of the MM2007 includes predefined basal rate and bolus amount maximums and is programmed to compare received delivery rates/amounts against these maximums, if the commanded amount is greater than its corresponding maximum, the delivery command is not executed.</p> <p>The MM2001 does not provide maximum rate limits in its IIA. Instead it provides, among other things, a maximum basal rate and a maximum bolus amount in its PPC. These maximum rate values are used to limit the rates programmable by the patient which result in a limit on the amount dispensable by the IIA.</p>
600. A programmable infusion system in accordance with claim 597, wherein said preselected medication infusion rate is remotely selectable.	<p>The IIA of the MM2007 can receive updated maximum values for basal rates and bolus amounts from its PPC through a Set Maximum Basal Rate telemetry command or Set Maximum Bolus Amount telemetry command, respectively. These maximum amounts may be programmed into the PPC either by a physician using a supervisor password or by a patient (if the physician sets the appropriate option to allow user programming).</p> <p>The MM2001 allows maximum bolus amount (up to 32 units of insulin) and maximum basal rate (up to 10 units/hour) to be programmed into its PPC.</p>
601. A programmable infusion system in accordance with claim 597, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.	<p>The IIA of the MM2007 can receive a physician/user predefined maximum basal rate value or maximum bolus amount from the PPC. In addition, as the basal rate and bolus commands are received by through RF telemetry with a predefined number of bits that can be used to specify basal and bolus amounts, a fixed upper limit exists that is dictated by the telemetry restrictions. This fixed upper limit sets a limit on the maximum basal rate value and maximum bolus amount that may be specified.</p> <p>The IIA of the MM2001 can pump at a predefined minimum number of seconds between pump strokes (about 5.6 seconds/stroke). As all pump strokes occur based on a currently programmed rate, without a memory for storing quantities of pump strokes that may be delivered at a later time, the minimum number of seconds between pump strokes is in effect a fixed maximum number of pump strokes per unit time (i.e. rate). This fixed maximum limits the effect of the programmable maximums. The PPC of the MM2001 provides an upper limit to the maximum basal rate that may be specified (10 units/Hr) and an upper limit to the maximum bolus amount that may be specified (32 units).</p>
618. A programmable infusion system in accordance with claim 538, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper operational conditions.	The IIA of the MM2007 generates a plurality of alarm patterns to control an audio alarm that is provided within the IIA. For example, this audio alarm is used to provide, among other things, a signal to the patient when the IIA is not operating properly. A first alarm pattern is used to warn the patient that the IIA is not operating in normal state (e.g. a low battery or low reservoir condition has arisen) while a second pattern is used to notify the patient that at least one of the

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	<p>microprocessors in the IIA was reset due to some form of malfunction and that the IIA has entered a non-delivery mode.</p> <p>The IIA of the MM2001 generates a plurality of audio alarms. For example, an audio alarm signal is initially generated with each bolus pump stroke when the battery is low and then after some time starts beeping with every bolus and every basal pump stroke. When the IIA monitoring system detects a hardware failure, an audio alarm is controlled to beep once a second for four minutes then to beep three times every fifteen minutes.</p>
619. A programmable infusion system in accordance with claim 618 further comprising means for delivering said alarm signal pattern to said living body subcutaneously.	The IIA of each system is intended to be implanted subcutaneously and as the alarm generation circuitry and the audio transducer (piezo electric element) are included therein, the alarm signal is applied to the body subcutaneously.
624. A programmable infusion system in accordance with claim 619, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means, wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
630. A programmable infusion system in accordance with claim 618, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means, said voltage determining means being coupled to said alarm generating means wherein one of said improper operational conditions comprises low battery means voltage.	<p>The IIA of each system includes a battery for powering the infusion mechanism and control electronics. The control electronics check the battery voltage periodically, and sound the IIA audio alarm if the battery voltage is "low".</p> <p>The IIA of the MM2007 uses an A/D converter to measure the battery voltage periodically. If a low battery voltage is detected, the MM2007 IIA first attempts to inform its PPC of the condition through use of the telemetry system but in the absence of receiving an acknowledgment from the PPC, the control electronics in the IIA cause the piezo alarm in the IIA to sound.</p>
633. A programmable infusion system in accordance with claim 538, further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.	The pressure on the medication reservoir is maintained at below normal atmospheric pressure (i.e. below the internal pressure of the living body) by maintaining a liquid -vapor volume of a selected material that has a pressure of vapor below atmospheric pressure (i.e. about - 4 psi)
634. A programmable infusion sytem in accordance with claim 633, wherein said pressure maintaining means comprises: a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-	The IIA of each system includes a bellows that is made from thin titanium sheets that collapse as insulin is extracted from the reservoir. The bellows separates the insulin containing chamber from a liquid-vapor volume/pool region that varies as insulin is removed from or added to the insulin containing chamber.

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vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.	
637. A programmable infusion system in accordance with claim 634, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable when the pressure in said antechamber exceeds the pressure in said medication chamber by more than a predetermined differential.	The IIA of each system does include an antechamber through which access is gained to the insulin containing chamber and the IIA does include an inlet valve located between the antechamber and the insulin chamber. The inlet valve is opened when the net pressure exerted by a refill needle pressing on the mechanism exceeds the pressure in the medication chamber by a predetermined amount.
638. A programmable infusion system in accordance with claim 637, wherein the volume of said antechamber is less than 10% the volume of said medication chamber.	The volume in the antechamber of each system is less than 10% of the volume of the insulin chamber.
640. A programmable infusion system in accordance with claim 538, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.	The IIA of each system dispenses insulin to the patient using fixed volume pulses.
<p>643. A programmable infusion system for providing medication to a living body of a patient comprising:</p> <p style="padding-left: 40px;">an infusion apparatus for implantation in said living body, said apparatus including¹</p> <p style="padding-left: 80px;">a medication reservoir for storing selected medication²,</p> <p style="padding-left: 40px;">means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having an infusion rate variable upon command,</p> <p style="padding-left: 40px;">command receiver means coupled to said infusion means for receiving command signals³, and</p> <p style="padding-left: 40px;">means for inhibiting said infusion means for infusing said selected medication if a preselected medication infusion rate is exceeded, said inhibiting means being operably coupled to said infusion means⁴; and</p> <p style="padding-left: 40px;">means for telemetering operational information pertaining to said infusion apparatus out of said living body⁵,</p> <p style="padding-left: 40px;">command source means external to</p>	<p>¹ The MM2001 and MM2007 are programmable infusion systems. Each of the MM2001 and MM2007 systems includes an implantable infusion apparatus (IIA) and an external communication device known as a Personal Pump Communicator (PPC). These systems dispense insulin to the body of a patient.</p> <p>² The IIA of each system (each of the MM2001 and MM2007 systems) includes an insulin (i.e. medication) reservoir.</p> <p>³ The IIA of each system includes software and control electronics that drive a pulsatile piston pump mechanism that dispenses a small volume of insulin with each stroke. The timing of and number of strokes dispensed by each IIA are controlled by commands received from its PPC.</p> <p>⁴ Each system provides mechanisms for inhibiting infusion of insulin if a predefined maximum infusion rate or amount is exceeded. The PPC of each system provides a way of selectively setting maximum basal rates and bolus amounts. These maximum amounts are used by the PPC to limit the amounts that may be programmed into the PPC for delivery by the IIA. Because of the telemetry connection between the PPC and its IIA, these maximum limits are operably coupled to the IIA. Furthermore, in the MM2007 system, these maximum amounts are also transmitted via telemetry to the IIA which uses them to ensure that telemetry messages are not acted upon if they contain delivery commands that call for amounts in excess of these limits. In addition, the MM2001 system is configured with a maximum pumping rate of about 10 strokes per minute.</p>

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<p>said living body for transmitting said command signals to be received by said command receiver means</p> <p>means for receiving said telemetered operational information external to said living body⁶.</p>	<p>⁵ The IIA for each system includes software, control electronics, and telemetry transmission hardware that enables transmission of information to its PPC. In the MM2001 this information includes current delivery parameters. In the MM2007 this information includes previous bolus amounts, extended bolus amounts and durations, daily basal and bolus totals</p> <p>⁶ The PPC for each system includes software, control electronics, and telemetry transmission and reception hardware that enables transmission of commands to its IIA and reception of information from the IIA. In the MM2001 this information includes current delivery parameters. In the MM2007 this information includes previous bolus amounts, extended bolus amounts and durations, daily basal and bolus totals</p>